Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)

**ADDENDUM:**

1. **Minor Change**
2. **Administrative change**
3. **Notifications of products in a biocidal product family**



Aquawood TIG

Product type 8

3-Iodo-2-propynyl butylcarbamat (IPBC) and Tebuconazole as included in the Union list of approved active substances

Case Numbers in R4BP:

a) BC-SH042156-39

b) BC-FC052020-77

c) BC-AK051895-34; BC-EK051898-24; BC-MJ051894-26;

BC-RU051897-93; BC-YL051896-06

Evaluating Competent Authority: eCA Austria

Date: 14/01/2020

Table of Contents

[1 Conclusion 3](#_Toc29471994)

[2 ASSESSMENT 4](#_Toc29471995)

[2.1 Background 4](#_Toc29471996)

[2.2 Description of changes 4](#_Toc29471997)

[2.2.1 Minor change (BC-SH042156-39) 4](#_Toc29471998)

[2.2.2 Administrative change (BC-FC052020-77) 5](#_Toc29471999)

[2.2.3 Notifications of products in a biocidal product family 5](#_Toc29472000)

[2.3 Evaluation of changes 6](#_Toc29472001)

[2.3.1 Minor change 6](#_Toc29472002)

[2.3.1.1 Identity and physico-chemical properties 6](#_Toc29472003)

[2.3.1.2 Authorised use and General directions of use 7](#_Toc29472004)

[2.3.1.3 Efficacy 7](#_Toc29472005)

[2.3.1.4 Human Health 11](#_Toc29472006)

[2.3.1.5 Environment 11](#_Toc29472007)

[2.3.2 Administrative change 11](#_Toc29472008)

[2.3.3 Notifications 11](#_Toc29472009)

[3 Annex 12](#_Toc29472010)

[3.1 List of studies 12](#_Toc29472011)

[3.1.1 Minor change 12](#_Toc29472012)

[3.2 Confidential information 14](#_Toc29472013)

[3.3 Confidential information restricted to authorities 14](#_Toc29472014)

# Conclusion

Evaluation of the minor change:

The product Aquawood TIM NG should be included into the BPF Aquawood TIG. The new product displays an increased water content and a decreased solid binder content compared to the original concentration range of the BPF.

The requirements of Reg. (EU) No 354/2013, Annex, TITLE 2, table line 2 are deemed to be fulfilled:

* Water (increased non-active substance) is not a substance of concern.
* The decrease of solid binder (reduction of the non-active substance) does not lead to an increase of an active substance or a substance of concern.
* The physical-chemical properties and the shelf-life of the products of the biocidal product family remain the same.
* The risk and efficacy profile are expected to remain the same.
* A new quantitative risk assessment is not expected to be necessary

The minor change is considered acceptable.

Evaluation of the administrative change:

The trade name “Aquawood Primo A5” is added for “Aquawood TIG HighRes Castagno” in AT. The change fulfils the requirements of Reg. (EU) No 354/2013, Annex, TITLE 1, SECTION 1, table line 2:

* Addition of a name for the biocidal product where there is no risk of confusion with other names of other biocidal products.

# ASSESSMENT

## Background

The authorisation holder ADLER Werk Lackfabrik Johann Berghofer GmbH & Co KG has applied for a minor change as well as for an administrative change in accordance with Regulation (EU) No 354/2013 to the authorised product family Aquawood TIG. Furthermore, products within the family were notified.

## Description of changes

### Minor change (BC-SH042156-39)

**The following minor change is applied for:**

A novel product (Aquawood TIM NG) shall be included into the already auhorised biocidal product family (BPF) Aquawood TIG.

The novel product differs from the other products by the decrease of the overall solid binder content and increase of water content. Regarding the solid binder content of the BPF it is based on different binders depending on the product in the BPF. The single binder used in the formulation of the novel product lies within the authorised range of the BPF for the respective binder. The increase of water lies not in the authorized range for the biocidal product family.

According to Reg. (EU) No 354/2013, Annex, TITLE 2, this is a minor change in composition and corresponds to the following table entry:

*“2. Increase, reduction, addition or deletion, or replacement of a non-active substance intentionally incorporated in a biocidal product family outside the authorised range, where:*

* *The added or increased non-active substance is not a substance of concern.*
* *The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern.*
* *The physical-chemical properties and the shelf-life of the products of the biocidal product family remain the same.*
* *The risk and efficacy profile are expected to remain the same.*
* *A new quantitative risk assessment is not expected to be necessary.”*

Only the water content range is changed, from 41.155-56.700% w/w in the current BPF to 41.155-79.600% w/w in the BPF after the minor change. In Aquawood TIM NG, the overall content of binder is decreased, compared to the other products of the family.

The requirements of Reg. (EU) No 354/2013, Annex, TITLE 2, table line 2 are deemed to be fulfilled:

* Water (increased non-active substance) is not a substance of concern.
* The decrease of solid binder (reduction of the non-active substance) does not lead to an increase of an active substance or a substance of concern.
* The physical-chemical properties and the shelf-life of the products of the biocidal product family remain the same. (cf. to chapter 2.3.1.1)
* The risk and efficacy profile are expected to remain the same. (cf. to chapter 2.3.1.3, 2.3.1.4, 2.3.1.5) The influence of binder decrease on efficacy has been assessed with other PT8 formulation to underline a justification stating that no change is to be expected.
* A new quantitative risk assessment is not expected to be necessary (cf. to chapter 2.3.1.4, 2.3.1.5) because exposure is not changed (same application rate, same active substance content…)

### Administrative change (BC-FC052020-77)

**The following administrative change is applied for:**

Addition of one trade name for “Aquawood TIG HighRes Castagno” in AT:

“Aquawood Primo A5”.

### Notifications of products in a biocidal product family

Notifications according to Reg. (EU) No. 528/2012, Article 17 (6):

Case no. BC-AK051895-34: Aquawood Primo A1

Case no. BC-EK051898-24: Aquawood Primo A4, Aquawood Primo A6, Aquawood Primo TIM, Aquawood TIG E1, Aquawood TIG E3, Aquawood TIG E4, Aquawood TIG E5

Case no. BC-MJ051894-26: Aquawood Ligno+ Base

Case no. BC-RU051897-93: Aquawood Primo A3, Aquawood Ligno+Base Eiche Natur

Case no. BC-YL051896-06: Aquawood Primo A2

## Evaluation of changes

### Minor change

#### Identity and physico-chemical properties

A novel product (Aquawood TIM NG) shall be included in the range of the already auhorised biocidal product family (BPF) Aquawood TIG. For the exact composition, please cf. to confidential annex.

The increase in solvent content (water) and the respective reduction in overall binder content are likely not to impact the physical or chemical endpoints assessed for the biocidal product family which contains waterbased products.

To demonstrate that the reduction in overall content of binder does not impact the claimed shelf life for new product, an accelerated storage test has been provided (Poscher et al. 2019). It was demonstrated that only negligible decrease of the active substances Teboconazole and IPBC occurs during the storage time of 4 weeks at 40°C and thus 1 year of shelf life may be accepeted. Furthermore, neither change in appearance of the product formulation nor impact on the packaging material was observed.

The submitted accelerated storage study (Poscher et al. 2019) has been performed using the novel product Aquawood TIM NG (formulation is stated under Composition of individual products in meta SPC 1 below).

|  |  |  |  |
| --- | --- | --- | --- |
| Aquawood TIM NG | Start (day 0) | 4 weeks at 40°C | 8 weeks at 40°C |
| IPBC | 0.75% | 0.71% | 0.68% |
| Tebuconazole | 0.37% | 0.36% | 0.38% |

After 4 weeks the reduction of IPBC was below 10% (5.4%) and equally after 8 weeks at 40°C the reduction fo IPBC was below 10% (9.4%).

Thus, the eCA concludes that the change in formulation acceptable.

#### Authorised use and General directions of use

No change.

#### Efficacy

The applicant has submitted a dossier with a biocidal product family containing 27 products. Of these 27 products two major formulations and a single formulation are present, with differing pigments. These backbone formulations comprised of Aquawood TIG E (11 different pigments), Aquawood HighRes (15 different pigments) and the single formulation Aquawood TIG mid-brown. Aquawood TIG E and Aquawood TIG HighRes differ in 13 coformulants which are either present in one of the both formulations but not in both. To bridge all products in the family by performing single efficacy tests a representative product was created namely Aquawood TIG the frame formulation. The frame formulation is a mixture of 50% v/v Aquawood TIG E and 50% v/v Aquawood TIG HighRes. Thus, the frame formulation contains all coformulants used in all the products present in the product family at 50% concentration but the same concentration of active substance. The justification for the frame formulation further included a statement depicting that all components which are not present in both formulations are only used at very low concentrations and subsequently do not impact the efficacy drastically.

This justification has been accepted in the first authorisation of the product family and is the base for the justification provided in the minor change.

During the minor change the eCA did evaluate the inclusion of the novel product in the product family. Following the rationale of the minor change the biocidal product family range of the initial authorisation is only changed for the water content.

Following the Annex A of the 599-1 a change of solvent is not explicitly part of the stated A.2.3 criteria to allow the waiving of additional tests for efficacy. Thus, subsequently A.4c would be triggered in which complete new testing of the product would be necessary. Following the change regulation the change is in its own right a minor change and thus no additional tests have been deemed necessary due to the stated expected similarity in efficacy.

Furthermore, we want to address that the decreased binder solid formulations are mainly aqueous formulations which contain around 30-50% of solid content. In case of Aquawood TIG high Res the overall binder content of 28% is reduced to 15% in the novel product to be incorporated into the biocidal product family. The binders used in Aquawood TIG High Res contain 30 and 50% solid respectively. Thus, it can be assumed that the majority of the substituted compounds from the binder formulations will be water.

Additionally the provided data on the binder reduction in formulations from a different company further included respective water content of 81.17 and 64.99. The formulation with 81.17% of water showed comparable efficacy.

These data prompted us to accept the minor change of the solvent content without the necessity of novel efficacy tests.

The reduction of binder is well within the authorised range. Thus, following the requirements of the regulation for minor changes no additional efficacy tests would be required for the inclusion of the product in the family range.

However, besides the requirements of the change regulation also the EN 599 is important for the change of formulations. And following the EN 599 Annex A the change of binder in the novel product (well within the range of the family) still exceeds 10% of total solid content. This would trigger according to the EN 599 simplified efficacy tests to demonstrate the impact of the change in solid content.

Five studies have been submitted to demonstrate that the decrease of binder would have no influence on the efficacy. The studies have not been performed by the applicant but another company using company owned products (JJT 6765, JJT 6775-1 & XSPP 001-1) which are not part of the BPF.

In two studies the EN 152 test for blue stain was performed (Fennert 2018, Fennert 2017). The used formulations contained three active substances IPBC, Tebuconazole and polymeric betaine. Both formulations share the same concentration of active substances and a comparable efficacy has been achieved. JJT 6765 contains 5% binder solid. JJT 6775-1 contains 10% binder solid. Furthermore, JJT 6775-1 contains additional coformulants.

To exclude a potential negative influence of the difference in coformulants the company has provided afurther study (Fennert 2009) using a formulation with two active substances (Tebuconazole & IPBC) and no coformulants but solid binder at 10%. The study was performed according to EN 113 & EN 84 and comparable results to the formulation from the applicant with 10% binder solid were achieved. Additionally, EN 113 & EN 84 studies with JJT 6765 and JJT 6775-1 were submitted (Souckova 2018a, Souckova 2018b). The active substance content between the three test formulations differed silightly as depicted in the following table. The table further includes the respective efficacy results from the EN 113 & EN 84. The difference in active substance content might be of lesser importance in regard to the antifungal function of IPBC and Tebuconazole.

|  |  |  |
| --- | --- | --- |
| EN113 EN 84 | | |
| **JJT 6765 (5% binder solid)** | **JJT 6775 (10.3% binder solid)** | **XSPP 0060 (12% binder solid)** |
| **Coformulants** | **Coformulants** | **No Coformulants** |
| **kg/m³** | **kg/m³** | **kg/m³** |
| 40.24 | 40.40 | 31 |
| **IPBC** | | |
| 0.9 | 0.9 | 0.7 |
| **Tebuconazole** | | |
| 0.25 | 0.25 | 0.4 |
| **Polymeric betaine** | | |
| 0.05 | 0.05 | --- |

The presented data from the three products of the different company which are not part of the biocidal product family demonstrate that the change of binder between 12 and 5% does not negatively impact the efficacy. And thus the tests were submitted to underline the justification to waive the requested EN 599 simplified efficacy trial.

At this point the eCA agreed with the applicant that the presented data on other products indicate that a reduction in solid binder content does not negatively impact the efficacy and thus the novel product Aquawood is to be expected to have a comparable efficacy than the frame formulation of Aquawood which is based on the used active substances.

However, the eCA further consulted with national experts on wood protection regarding this matter (Holzforschung Austria). The national expert agreed with the justification stating that solid binder content may negatively impact the efficacy due to change in dispersion and penetrating ability of the product on the wood above roughly 20% of solid content. Changing between 12 and 5% will not influence the efficacy given that no other coformulant is changed.  Solid binder is solely used to facilitate the dispersion during application of the product. The penetrating ability is not influenced below approximately 20% of solid binder content.

| **Field of use envisaged** | **Test substance** | **Test method** | **Test system / concentrations applied / exposure time** | **Test organism(s)** | **Test results: effects** | | **Reference** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Limit of efficacy / toxic value / threshold value** | |
| *Treatment solution* | Preservative concentrate |
| PT 8 | JJT 6765 | EN 152 | * Brushing, 110 – 120 ml/m², 3 coatings * Test is valid significant blue stain in control samples * 4 weeks of artificial weathering | *Aureobasidium pullulans*  *Sydowia polyspora* | *100%* | 2 x 0 (no blue stain)  4 x 1 (insignificantly blue-stained) | Fennert et. Al. 2017 |
| PT 8 | JJT 6775-1 | EN 152 | * Test product dipping 3 – 15 min * Reference product brushing * Test is valid significant blue stain in control samples * 4 weeks of artificial weathering | *Aureobasidium pullulans*  *Sydowia polyspora* | *100%* | 5 x 0 (no blue stain)  1 x 1 (insignificantly blue-stained) | Fennert et. Al. 2018 |
| PT 8 | XSPP 0060 | EN 113 & EN 84 | Vaccum pressure treatment  0 – 3,9 – 4,6- 5,9- 7,2- 9,1% retention of test product tested  Test is valid mass reduction of control samples is sufficient | *Coniophora puteana*  *Poria placenta*  *Gloeophyllum trabeum* | *3.9% retention* | Coniophora puteana 31 kg/m³  Poria placenta 31.1 kg/m³  Gloeophyllum trabeum 31 kg/m³ | Fennert et. Al. 2009 |
| PT 8 | JJT 6765 | EN 113 & EN 84 | Vaccum pressure treatment  0 – 4,8- 6- 7.2 – 8.4 – 9.6% retention of test product tested  Test is valid mass reduction of control samples is sufficient | *Coniophora puteana*  *Poria placenta*  *Gloeophyllum trabeum* | *4.8% retention* | Coniophora puteana 40.24 kg/m³  Poria placenta 39.6 kg/m³  Gloeophyllum trabeum 39.78 kg/m³ | Souckova 2018a |
| PT 8 | JJT 6775 | EN 113 & EN 84 | Vaccum pressure treatment  0 – 4,8- 6- 7.2 – 8.4 – 9.6% retention of test product tested  Test is valid mass reduction of control samples is sufficient | *Coniophora puteana*  *Poria placenta*  *Gloeophyllum trabeum* | *4.8% retention* | Coniophora puteana 40.40 kg/m³  Poria placenta 39.75 kg/m³  Gloeophyllum trabeum 40.56 kg/m³ | Souckova 2018b |

The eCA is primed to accept the justification based on the provided studies and in use experience.

#### Human Health

No change. As the active substance content as well as the use and application rates stay the same, and as no subtances of concern are contained in the product, the original human exposure and risk assessment also covers the new product.

#### Environment

No change. As the active substance content as well as the use and application rates stay the same, and as no subtances of concern are contained in the product, the original environmental exposure and risk assessment also covers the new product.

### Administrative change

The change fulfils the requirements of Reg. (EU) No 354/2013, Annex, TITLE 1, SECTION 1, table line 2:

Addition of a name for the biocidal product where there is no risk of confusion with other names of other biocidal products.

### Notifications

Full compositions: See confidential annex.

# Annex

## List of studies

### Minor change

| **Author** | **Year** | **Title** | **Testing Company** | **Report No.** | **GLP Study** | **Data Protection Claimed** | **Data Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Poscher et al. | 2019 | Accelerated Storage Stability  of Aquawood TIM NG | Lanxess Deutschland GmbH | JJT6851 | no | yes | ADLER Werk Lackfabrik Johann Berghofer GmbH & Co KG |
| Fennert et al. | 2018 | Laboratory method for determining the protective effectiveness of a preservative treatment against blue atin according to EN 152 (2011) after 4 weeks artificial weathering | MPA Eberswalde | 32/17/10133/01 | no | yes | ADLER Werk Lackfabrik Johann Berghofer GmbH & Co KG |
| Fennert et al. | 2017 | Laboratory method for determining the protective effectiveness of a preservative treatment against blue atin according to EN 152 (2011) after 1 week artificial weathering | MPA Eberswalde | 32/17/10082/01 | no | yes | ADLER Werk Lackfabrik Johann Berghofer GmbH & Co KG |
| Souckova 2018a | 2018 | Test report No. MVZ-A-2018-000329 | Timber Research and Development Institute Praha | MVZ-A-2018-000333 | no | yes | ADLER Werk Lackfabrik Johann Berghofer GmbH & Co KG |
| Souckova 2018b | 2018 | Test report No. MVZ-A-2018-000333 | Timber Research and Development Institute Praha | MVZ-A-2018-000333 | no | yes | ADLER Werk Lackfabrik Johann Berghofer GmbH & Co KG |
| Fennert et al. | 2009 | Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (11/96) in combination with leaching procedure according to EN 84 (05/97) | MPA Eberswalde | 32/08/9153/01 | no | yes | ADLER Werk Lackfabrik Johann Berghofer GmbH & Co KG |

## Confidential information

See confidential Annex.

## Confidential information restricted to authorities

See confidential Annex restricted to authorities.